

specimen to the pad for the purpose of precisely identifying the anatomical location from which the specimen was removed and for transporting the location-identified specimen to a laboratory for pathology or histological analysis as set forth in the specification. Being a design patent, Leslie has no real description but only a title, and the title is "Breast Examination Pad". This apparently is not a gross pathology breast map as now described and claimed, but rather a flexible pad with a nipple hole, for placement over the breast to mark the pad during a breast examination.

Taking first claim 1, Leslie does not show or describe a top layer which includes a substantially hard, suturable, tackable material. The top layer 10 of the Lary's specimen board is a sheet of smooth paper, and the layer beneath is a foam core. If the paper is the top layer, this paper layer is not hard and suturable because Lary attaches the excised specimen to the board in a different manner from the current invention, by placing the specimen on the specimen board on the absorbent square 22 "to which it naturally adheres" (col. 4, lines 37-38).

The absorbent square 22 of Lary is better considered as the top layer of Lary for purpose of comparison to the current claims. But still, this does not meet the structural limitations of claim 1. The absorbent square 22 is adhesively attached to the specimen board 10, to the outer paper layer 18 of the

specimen board. Again, the absorbent square does not meet the definition in the claim of being a substantially hard, suturable, tackable material. It is intended to receive directly a tissue specimen, which will naturally adhere to it.

Further, Lary's top layer does not include a graphic representation of a breast anatomy. Lary's absorbent square is actually blank, but with row and column-identifying indicia at 28 and 30 in the top horizontal margin and left vertical margin of the square. In Figure 3 Lary shows a sheet of paper for the physician to identify the location for which the specimen was taken, by entry of information using a pen or pencil. This is, as described in Lary, a sheet of paper 44 that is furnished along with the specimen board 10. Thus, the instrument 44 having indicia comprising vertical and horizontal indicia for location identification is a separate instrument from the instrument on which the specimen is actually adhered.

On top of all this, Lary does not include a nipple as part of a graphic representation in the top layer, nor an axilla on the graphic representation (and there is no graphic representation).

It is noted that in the Examiner's action the top layer and second layer of the applicant's claims were considered as being the layer 10 and the layer 20 in Lary. However, this cannot really be the case because the applicant's top layer is a top

layer, and the second layer is beneath and thus, the elements 10 and 20 of Lary cannot be read on claim 1. The layer 20 in Lary is actually a cover, hingedly attached to the specimen board 10 and to be closed over and against the specimen after the specimen is adhered onto the absorbent square 22, holding the specimen in place until further analytic work is to be done.

The applicant's claim 1 clearly defines a top layer which is on top, and a second layer which is beneath the top layer. If the second layer were on top, the "top layer" could not be described as a top layer.

A nipple and axilla are shown on the Leslie design patent, but it is not believed that this design patent is particularly relevant here because it does not appear to be for the same purpose (but only for a physical examination function) and thus would not inspire one of skill in the medical arts to modify or improve on the Lary device. In addition, as pointed out above, this combination still would not produce the invention as claimed primarily because of the different nature of the top layer in Lary and the lack of a graphic representation of a breast anatomy.

It is also pointed out that the "second layer" in Lary, which could be considered the foam core 20 of the board 10 with the paper layer 18 on top (or it could simply be considered the paper layer 18), does not have a back surface that comprises

radio-opaque elements that correspond to the graphic representation of the top layer. For one thing, there is no graphic representation on the top layer, and for another, there is no radio-opaque pattern of elements on the back which correspond to anything on the front layer.

It seems clear claim 1 defines a very different structure from what is shown in Lary, and any attempt to combine Leslie with Lary would not result in the elements recited in claim 1 (and the other claims of this application), even if one would be inspired to make such a combination, which is not the case. Claim 1 should be allowable.

Claim 2 is allowable for the same reasons presented for claim 1. Claim 2 includes similar features, with the exception that the second layer is not described as having a back surface with radio-opaque elements corresponding to the graphic representation of the top layer. Instead, claim 2 recites a third layer affixed to and aligned with the second layer, the third layer having the radio-opaque markers that correspond to the graphic representation on the top layer. This combination differs from Lary in essentially the same way as described above. Note also that Lary's second layer (either the paper layer or the paper/foam core sandwich together) does not appear to be and is not described as an absorptive, suturable, tackable material, as recited in these claims.

Also note that in claim 2 that the front of Lary's sheet 82 cannot be considered the third layer defined in claim 2. The claim recites a top layer, a second layer and a third layer, and this clearly means the second and third layers are below the top layer, otherwise the top layer could not be called a top layer. The element 82 of Lary is the "closed specimen board and compression sheet combination". In other words, it is the apparatus in Figure 1 with the top flap closed over the specimen board 10, and with a specimen adhered to the absorbent square and sandwiched between the compression sheet and the specimen board. The focusing target 84 shown in Figure 4 of Lary is printed on the back of the compression sheet 12, thus visible after the compression sheet has been closed over the specimen board. This focusing target is to coincide with the center of the absorbent square 22 inside. This is simply a center location for use of a radiologist in taking radiological images. It is clearly not the third layer as defined in claim 2 and does not include radio-opaque markers that correspond to a graphic representation on the top layer - there is no graphic representation in Lary.

Claim 3 is a method claim directed to a method for radiographically and histologically examining a breast tissue specimen while recording and maintaining the anatomical location of the specimen to the breast. Although Lary discloses his own method aimed at somewhat the same result, Lary does not disclose

affixing the tissue specimen on a gross pathology breast map, because he does not disclose a gross breast pathology breast map on his specimen board but merely a blank absorbent square that has some identifying column and line indicia at top and left margins. One can see from column 4 of Lary that the first step after identifying suspicious lesions and establishing their location temporarily using a localizing needle, is to use the diagrams of Figure 3 to note the position using the matrix of lines on the diagrams. After that is done, a specimen is removed and placed on the specimen board, on the absorbent square (which is blank) to which the specimen naturally adheres. The claim distinguishes from the prior art.

Method claim 5 should also be allowed. Claim 5 includes the steps noted above relative to claim 3, and also the step of identifying margins of the tissue specimen, and, importantly, the step of removing the radiosensitive back layer from the gross pathology breast map and including that layer in the patient's chart as a record. Lary does not disclose any such radiosensitive back layer, nor does he disclose a step of removing such a back layer and including it in a patient's chart.

Claim 6 recites a "kit" for examining a breast tissue specimen. The kit of components includes a gross pathology breast map, which Lary does not include and Leslie fails to suggest because Leslie comprises a pad to be laid over the breast

to note portions examined. Lary does disclose a container or enclosure 70, a flat polyethylene bag having a re-sealable closure at its top. It may or may not be leakproof. The combination defined in claim 6 is not contemplated by or suggested by Lary or any attempted combination of Lary with Leslie.

It is thus submitted that all of claims 1-6 define a patentable invention over the cited art and the rejected claims, along with claim 4, should be allowed. Favorable action is solicited. However, if the Examiner believes any issue remains, he is asked to telephone the undersigned attorney before issuing a further action.

Respectfully submitted,



Date: January 24, 2008

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